

**That Which Is Claimed Is:**

1. A pharmaceutical composition for the treatment of female sexual dysfunction, said composition comprising:

- a therapeutically effective amount of an estrogenic compound;
- a therapeutically effective amount of an androgenic compound;
- a therapeutically effective amount of a vasodilation compound; and
- a pharmaceutically acceptable carrier.

2. The pharmaceutical composition according to Claim 1, wherein the estrogenic compound is selected from the group consisting of estrone, 17 $\alpha$ -estradiol, 17 $\beta$ -estradiol, equilin, 17 $\alpha$ -dihydroequilin, 17 $\beta$ -dihydroequilin, equilenin, 17 $\alpha$ -dihydroequilenin, 17 $\beta$ -dihydroequilenin,  $\Delta^{8,9}$ -dehydroestrone, 17 $\alpha$ - $\Delta^{8,9}$ -dehydroestradiol, 17 $\beta$ - $\Delta^{8,9}$ -dehydroestradiol, ethinyl estradiol, estradiol valerate, 6-OH equilenin, 6-OH 17 $\alpha$ -dihydroequilenin, 6-OH 17 $\beta$ -dihydroequilenin, and mixtures, conjugates and salts thereof.

3. The pharmaceutical composition according to Claim 1, wherein the androgenic compound is selected from the group consisting of methyltestosterone, androsterone, androsterone acetate, androstenedione, androstanediol, androsterone propionate, androsterone benzoate, androsteronediol, androsteronediol-3-acetate, androsteronediol-17-acetate, androsteronediol 3,17-diacetate, androsteronediol-17-benzoate, androsteronediol-3-acetate-17-benzoate, androsteronediol, dehydroepiandrosterone, sodium dehydroepiandrosterone sulfate, dromostanolone, dromostanolone propionate, ethylestrenol, fluoxymesterone, deridicale, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, oxandrolone, oxymetholone, stanozolol, testosterone, 17 $\alpha$ -methyl-19-nortestosterone, testosterone decanoate, 4-dihydrotestosterone, 5 $\alpha$ -dihydrotestosterone, testolactone, pharmaceutically acceptable esters and salts thereof, and combinations of any of the foregoing.

4. The pharmaceutical composition according to Claim 1, wherein the vasodilation compound is an alpha adrenergic antagonists.

5. The pharmaceutical composition according to Claim 4, wherein the alpha adrenergic antagonist is phentolamine mesylate or phentolamine hydrochloride.

6. The pharmaceutical composition according to Claim 4, wherein the vasodilation compound further comprises apomorphine.

7. The pharmaceutical composition according to Claim 1, further comprising a therapeutically effective amount of a progestin compound.

8. The pharmaceutical composition according to Claim 7, wherein the progestin compound is selected from the group consisting of desogestrel, dydrogesterone, ethynodiol diacetate, medroxyprogesterone, levonorgestrel, medroxyprogesterone acetate, hydroxyprogesterone caproate, norethindrone, norethindrone acetate, norethynodrel, allylestrenol, 19-nortestosterone, lynoestrenol, quingestanol acetate, medrogestone, norgestriene, dimethisterone, ethisterone, cyproterone acetate, chlormadinone acetate, megestrol acetate, norgestimate, norgestrel, desogestrel, trimegestone, gestodene, nomegestrol acetate; nomegestrol progestrone, 5 $\alpha$ -pregnan-3 $\beta$ , 20 $\alpha$ -diol sulfate, 5 $\alpha$ -pregnan-3 $\beta$ , 20 $\beta$ -diol sulfate, 5 $\alpha$ -pregnan-3 $\beta$ -ol-20-one, 16,5 $\alpha$ -pregnen-3 $\beta$ -ol-20-one, 4-pregnen-20 $\beta$ -ol-3-one-20-sulfate, acetoxy pregnenolone, anagestone acetate, cyproterone, dihydrogesterone, flurogestone acetate, gestadene, hydroxyprogesterone acetate, hydroxymethylprogesterone, hydroxymethyl progesterone acetate, 3-ketodesogestrel, megestrol, melengestrol acetate, norethisterone and mixtures thereof.

9. A pharmaceutical composition for the treatment of female sexual dysfunction in a pre-menopausal female, said composition comprising:  
a therapeutically effective amount of an androgenic compound;  
a therapeutically effective amount of a vasodilation compound; and  
a pharmaceutically acceptable carrier.

10. The pharmaceutical composition according to Claim 9, wherein the androgenic compound is selected from the group consisting of methyltestosterone, androstenedione, androstenediol, androsterone, androsterone acetate, androsterone propionate, androsterone benzoate, androsteronediol, androsteronediol-3-acetate, androsteronediol-17-acetate, androsteronediol 3,17-diacetate, androsteronediol-17-benzoate, androsteronediol-3-acetate-17-benzoate, androsteronedione, dehydroepiandrosterone, sodium dehydroepiandrosterone sulfate, dromostanolone, dromostanolone propionate, ethylestrenol, fluoxymesterone, deridcale, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, oxandrolone, oxymetholone, stanozolol, testosterone, 17 $\alpha$ -methyl-19-nortestosterone, testosterone decanoate, 4-dihydrotestosterone, 5 $\alpha$ -dihydrotestosterone, testolactone, pharmaceutically acceptable esters and salts thereof, and combinations of any of the foregoing.

11. The pharmaceutical composition according to Claim 9, wherein vasodilation compound is an alpha adrenergic antagonist.

12. The pharmaceutical composition according to Claim 11, wherein the alpha adrenergic antagonist is phentolamine mesylate or phentolamine hydrochloride.

13. The pharmaceutical composition according to Claim 12, wherein the vasodilation compound further comprises apomorphine.

14. The pharmaceutical composition according to Claim 9, further comprising a therapeutically effective amount of a progestin compound.

15. The pharmaceutical composition according to Claim 15, wherein the progestin compound is selected from the group consisting of desogestrel, hydrogesterone, ethynodiol diacetate, medroxyprogesterone, levonorgestrel, medroxyprogesterone acetate, hydroxyprogesterone caproate, norethindrone, norethindrone acetate, norethynodrel, allylestrenol, 19-nortestosterone, lynoestrenol, quingestanol acetate, medrogestone, norgestriene, dimethisterone, ethisterone, cyproterone acetate, chlormadinone acetate, megestrol acetate, norgestimate, norgestrel,

desogestrel, trimegestone, gestodene, nomegestrol acetate, nomegestrol progesterone, 5 $\alpha$ -pregnan-3 $\beta$ , 20 $\alpha$ -diol sulfate, 5 $\alpha$ -pregnan-3 $\beta$ , 20 $\beta$ -diol sulfate, 5 $\alpha$ -pregnan-3 $\beta$ -ol-20-one, 16,5 $\alpha$ -pregnen-3 $\beta$ -ol-20-one, 4-pregnen-20 $\beta$ -ol-3-one-20-sulfate, acetoxypregnolone, anagestone acetate, cyproterone, dihydrogesterone, flurogestone acetate, gestadene, hydroxyprogesterone acetate, hydroxymethylprogesterone, hydroxymethyl progesterone acetate, 3-ketodesogestrel, megestrol, melengestrol acetate, norethisterone and mixtures thereof.

16. A pharmaceutical formulation for treating female sexual dysfunction comprising:

a therapeutically effective amount of an estrogenic compound;  
a therapeutically effective amount of an androgenic compound;  
a pharmaceutically acceptable carrier; and  
a therapeutically effective amount of a vasodilation compound administered on a performance-on-demand basis.

17. A method of treating female sexual dysfunction in a female in need of such treatment, said method comprising:

administering a combination of a therapeutically effective amount of an estrogenic compound and a therapeutically effective amount of an androgenic compound to the female; and

administering a therapeutically effective amount of a vasodilation compound to the female.

18. The method according to Claim 17, wherein the combination of a therapeutically effective amount of an estrogenic compound and a therapeutically effective amount of an androgenic compound is administered on a chronic basis, and wherein the therapeutically effective amount of a vasodilation compound is administered on a chronic basis.

19. The method according to Claim 17, wherein the combination of a therapeutically effective amount of an estrogenic compound and a therapeutically effective amount of an androgenic compound, and the therapeutically effective amount of a vasodilation compound are administered simultaneously.

20. The method according to Claim 17, wherein the combination of administering the therapeutically effective amount of an estrogenic compound and the therapeutically effective amount of an androgenic compound, and administering the therapeutically effective amount of a vasodilation compound is administered in tablet form.

21. The method according to Claim 17, wherein the combination of a therapeutically effective amount of an estrogenic compound and a therapeutically effective amount of an androgenic compound is administered in a tablet form, and wherein the therapeutically effective amount of a vasodilation compound is administered in a topical form.

22. The method according to Claim 17, wherein the combination of a therapeutically effective amount of an estrogenic compound and a therapeutically effective amount of an androgenic compound is administered on a chronic basis, and wherein the therapeutically effective amount of a vasodilation compound is administered on a performance-on-demand basis.

23. The method according to Claim 17, wherein the combination of a therapeutically effective amount of an estrogenic compound and a therapeutically effective amount of an androgenic compound is administered in a tablet form, and wherein the therapeutically effective amount of a vasodilation compound is administered in a tablet form.

24. The method according to Claim 17, wherein the combination of a therapeutically effective amount of an estrogenic compound and a therapeutically effective amount of an androgenic compound is administered in a tablet form, and wherein the therapeutically effective amount of a vasodilation compound is administered in a topical form.

25. The method according to Claim 24, wherein the topical form is selected from the group consisting of patches, gels, and creams.

26. The method according to Claim 25, wherein the topical form is applied to the skin.

27. The method according to Claim 25, wherein the topical form is applied to the vagina.

28. The method according to Claim 17, wherein the estrogenic compound is selected from the group consisting of estrone,  $17\alpha$ -estradiol,  $17\beta$ -estradiol, equilin,  $17\alpha$ -dihydroequilin,  $17\beta$ -dihydroequilin, equilenin,  $17\alpha$ -dihydroequilenin,  $17\beta$ -dihydroequilenin,  $\Delta^{8,9}$ -dehydroestrone,  $17\alpha$ - $\Delta^{8,9}$ -dehydroestradiol,  $17\beta$ - $\Delta^{8,9}$ -dehydroestradiol, ethinyl estradiol, estradiol valerate, 6-OH equilenin, 6-OH  $17\alpha$ -dihydroequilenin, 6-OH  $17\beta$ -dihydroequilenin, and mixtures, conjugates and salts thereof.

29. The method according to Claim 17, wherein the androgenic compound is selected from the group consisting of methyltestosterone, androstenedione, androstenediol, androsterone, androsterone acetate, androsterone propionate, androsterone benzoate, androsteronediol, androsteronediol-3-acetate, androsteronediol-17-acetate, androsteronediol 3,17-diacetate, androsteronediol-17-benzoate, androsteronediol-3-acetate-17-benzoate, androsteronedione, dehydroepiandrosterone, sodium dehydroepiandrosterone sulfate, dromostanolone, dromostanolone propionate, ethylestrenol, fluoxymesterone, deridicale, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, oxandrolone, oxymetholone, stanozolol, testosterone,  $17\alpha$ -methyl-19-nortestosterone, testosterone decanoate, 4-dihydrotestosterone,  $5\alpha$ -dihydrotestosterone, testolactone, pharmaceutically acceptable esters and salts thereof, and combinations of any of the foregoing.

30. The method according to Claim 17, wherein the vasodilation compound is an alpha adrenergic antagonist.

31. The method according to Claim 30, wherein the vasodilation compound is phentolamine mesylate or phenolamine hydrochloride.

32. The method according to Claim 31, wherein the vasodilation compound further comprises apomorphine.

33. The method according to Claim 17, further comprising administering a therapeutically effective amount of a progestin compound to the female.

34. The method according to Claim 33, wherein the progestin compound is selected from the group consisting of desogestrel, dydrogesterone, ethynodiol diacetate, medroxyprogesterone, levonorgestrel, medroxyprogesterone acetate, hydroxyprogesterone caproate, norethindrone, norethindrone acetate, norethynodrel, allylestrenol, 19-nortestosterone, lynoestrenol, quingestanol acetate, medrogestone, norgestriene, dimethisterone, ethisterone, cyproterone acetate, chlormadinone acetate, megestrol acetate, norgestimate, norgestrel, desogestrel, trimegestone, gestodene, nomegestrol acetate, nomegestrol, progesterone,  $5\alpha$ -pregnan-3 $\beta$ , 20 $\alpha$ -diol sulfate,  $5\alpha$ -pregnan-3 $\beta$ , 20 $\beta$ -diol sulfate,  $5\alpha$ -pregnan-3 $\beta$ -ol-20-one, 16,5 $\alpha$ -pregnen-3 $\beta$ -ol-20-one, 4-pregnen-20 $\beta$ -ol-3-one-20-sulfate, acetoxy pregnenolone, anagestone acetate, cyproterone, dihydrogesterone, flurogestone acetate, gestadene, hydroxyprogesterone acetate, hydroxymethylprogesterone, hydroxymethyl progesterone acetate, 3-ketodesogestrel, megestrol, melengestrol acetate, norethisterone and mixtures thereof.

35. A method of treating female sexual dysfunction in a pre-menopausal female in need of such treatment, said method comprising:

administering a therapeutically effective amount of an androgenic compound to the female; and

administering a therapeutically effective amount of a vasodilation compound to the female.

36. The method according to Claim 35, wherein the therapeutically effective amount of an androgenic compound is administered on a chronic basis, and wherein the therapeutically effective amount of a vasodilation compound is administered on a chronic basis.

37. The method according to Claim 36, wherein the therapeutically effective amount of an androgenic compound and the therapeutically effective amount of a vasodilation compound are administered as a combination.

38. The method according to Claim 37, wherein the combination is administered in tablet form.

39. The method according to Claim 35, wherein the therapeutically effective amount of an androgenic compound is administered in a tablet form, and wherein the therapeutically effective amount of a vasodilation compound is administered in a topical form.

40. The method according to Claim 35, wherein the therapeutically effective amount of an androgenic compound is administered on a chronic basis, and wherein the therapeutically effective amount of a vasodilation compound is administered on a performance-on-demand basis.

41. The method according to Claim 35, wherein the therapeutically effective amount of an androgenic compound is administered in a tablet form, and wherein the therapeutically effective amount of a vasodilation compound is administered in a tablet form

42. The method according to Claim 35, wherein the therapeutically effective amount of an androgenic compound is administered in a tablet form, and wherein the therapeutically effective amount of a vasodilation compound is administered in a topical form.

43. The method according to Claim 42, wherein the topical form is selected from the group consisting of patches, gels, and creams.

44. The method according to Claim 42, wherein the topical form is applied to the skin.

45. The method according to Claim 42, wherein the topical form is applied to the vagina.

46. The method according to Claim 35, wherein the androgenic compound is selected from the group consisting of methyltestosterone, androstenedione, androstenediol, androsterone, androsterone acetate, androsterone propionate, androsterone benzoate, androsteronediol, androsteronediol-3-acetate, androsteronediol-17-acetate, androsteronediol 3,17-diacetate, androsteronediol-17-benzoate, androsteronediol-3-acetate-17-benzoate, androsteronedione, dehydroepiandrosterone, sodium dehydroepiandrosterone sulfate, dromostanolone, dromostanolone propionate, ethylestrenol, fluoxymesterone, deridale, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, oxandrolone, oxymetholone, stanozolol, testosterone, 17 $\alpha$ -methyl-19-nortestosterone, testosterone decanoate, 4-dihydrotestosterone, 5 $\alpha$ -dihydrotestosterone, testolactone, pharmaceutically acceptable esters and salts thereof, and combinations of any of the foregoing.

47. The method according to Claim 35, wherein the vasodilation compound is an alpha adrenergic antagonist.

48. The method according to Claim 47, wherein the alpha adrenergic antagonist is phentolamine.

49. The method according to Claim 47, where in the vasodilation compound further comprises apomorphine.

50. The method according to Claim 35, further comprising administering a therapeutically effective amount of a progestin compound to the female.

51. The method according to Claim 50, wherein the progestin compound is selected from the group consisting of desogestrel, dydrogesterone, ethynodiol diacetate, medroxyprogesterone, levonorgestrel, medroxyprogesterone acetate, hydroxyprogesterone caproate, norethindrone, norethindrone acetate, norethynodrel, allylestrenol, 19-nortestosterone, lynoestrenol, quingestanol acetate, medrogestone,

norgestrienedione, dimethisterone, ethisterone, cyproterone acetate, chlormadinone acetate, megestrol acetate, norgestimate, norgestrel, desogestrel, trimegestone, gestodene, nomegestrol acetate, nomegestrol, progesterone,  $5\alpha$ -pregnan-3 $\beta$ , 20 $\alpha$ -diol sulfate,  $5\alpha$ -pregnan-3 $\beta$ , 20 $\beta$ -diol sulfate,  $5\alpha$ -pregnan-3 $\beta$ -ol-20-one, 16,5 $\alpha$ -pregnen-3 $\beta$ -ol-20-one, 4-pregnen-20 $\beta$ -ol-3-one-20-sulfate, acetoxyprogrenolone, anagestone acetate, cyproterone, dihydrogesterone, flurogestone acetate, gestadene, hydroxyprogesterone acetate, hydroxymethylprogesterone, hydroxymethyl progesterone acetate, 3-ketodesogestrel, megestrol, melengestrol acetate, norethisterone and mixtures thereof.

2020 RELEASE UNDER E.O. 14176